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ALSTON & BIRD LLP
PIONEER HI-BRED INTERNATIONAL, INC.
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

AHMED, HASAN SYED

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1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Receipt is acknowledged of applicants' remarks, filed on 6 August 2010.

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Claim Objections

Claims 15 and 27 are objected to because of the following informalities: the word "grain" is misspelled as "grin". Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 12-16, 20, 21, and 27-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,244,877 ("Eenennaam") in view of U.S. 2002/0151733 ("Ulrich"), further in view of U.S. 2002/0108148 ("Boronat") (the later two references are currently of-record).

Independent claim 1 recites a method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising at least 150 ppm mixed tocotrienols.

Independent claim 20 recites a method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising 50 ppm to 500 ppm mixed tocotrienols.

Eenennaam teaches methods for the production of transgenic plants (see abstract). The disclosed transgenic plants may be processed to produce a feed, meal protein, or oil preparation designed for ruminant animals (see, e.g., col. 6, lines 48-67), reading on the diet of claim 1, and the animals (i.e., ruminant animals, see col. 34, line 30) of claims 12 and 13 (since cattle are ruminant animals). While the prior art reference does not explicitly teach a feeding step, it would be obvious to a person of ordinary skill in the art to feed a ruminant animal a feed, meal, protein, or oil preparation which is designed for ruminant animals; Eenennaam states, “[i]n a preferred embodiment the feed, meal, protein or oil preparation is designed for ruminant animals.” See col. 34, lines 29-30.

Regarding the mixed tocotrienols of claims 1 and 20, Eenennaam teaches that one or more products of the tocopherol biosynthesis pathway, including any one or more of tocotrienols, alpha-tocotrienols, gamma-tocotrienols, delta-tocotrienols, and beta-tocotrienols are increased throughout an organism such as a plant, preferably in a seed (see col. 22, lines 52-56).

Eenennaam teaches genetically modifying plants to increase levels of tocotrienols such as alpha-tocotrienols, gamma-tocotrienols, delta-tocotrienols, and beta-tocotrienols, reading on claims 14 and 27 (see col. 13, lines 29-56; col. 22, lines 52-56, col. 38, line 60-col. 39, line 6; examples 1, 3, 4; and claims 17, 19, 28, 31, and 21). An example of a genetically modified cereal grain crop disclosed by Eenennaam is corn, reading on claims 15 and 28 (see col. 13, lines 29-56; col. 22, lines 52-56, col. 38, line 60-col. 39, line 6; examples 1, 3, 4; and claims 17, 19, 28, 31, and 21). Eenennaam

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further teaches oil derived from a seed of the disclosed transformed plant (see col. 6, lines 48-54).

Eenennaam explains that the disclosed invention is beneficial because, “[t]here is a...need for transgenic organisms expressing...nucleic acid molecules involved in tocopherol biosynthesis, which are capable of nutritionally enhancing food and feed sources.” See col. 4, lines 28-32.

The improved tissue quality of instant claims 1 and 20 and oxidative stability of instant claims 2 and 21 are inherent features of tocotrienols as shown by Boronat (see [0005]).

Eenennaam differs from the instant application in that it does not explicitly disclose the at least 150 ppm mixed tocotrienol concentration of instant claim 1 and the 50 ppm to 500 ppm tocotrienol concentration range of instant claims 20, 27, and 29. It is noted that claims 1, 20, 27, and 29 do not recite amounts of specific tocotrienols, only a concentration range of mixed tocotrienols. Ulrich shows that yellow corn oil contains 231 ppm of alpha-tocotrienol, 23 ppm of beta-tocotrienol, 1463 ppm of gamma-tocotrienol, and 63 ppm of delta-tocotrienol (see Table 3). In one embodiment, Eenennaam teaches a 10% increase in tocotrienols with the disclosed transformed plant (see col. 22, line 54). A 10% increase of 231 ppm of alpha-tocotrienol, 23 ppm of beta-tocotrienol, and 63 ppm of delta-tocotrienol would result in a mixed tocotrienol concentration above the 150 ppm of instant claim 1 and overlapping with the 50 ppm to 500 ppm range of claims 20, 27, and 29. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists.

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In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a method of improving the tissue quality of an animal, comprising feeding the animal a diet of at least 150 ppm mixed tocotrienols, or 50 ppm to 500 ppm mixed tocotrienols, as taught by Eenennaam in view of Ulrich. One of ordinary skill in the art at the time the invention was made would have been motivated to use such a method because a diet comprising elevated tocotrienols results in nutritionally enhanced food and feed sources, as explained by Eenennaam (see above).

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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1. Claims 1, 2, 12-16, 20, 21, and 27-29 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/153,463 ('463). Although the conflicting claims are not identical, they are not patentably distinct from each other because '463 claims a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols. See claims 1, 12, and 19.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*

2. Claims 1, 2, 12-16, 20, 21, and 27-29 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/530,075 ('075). Although the conflicting claims are not identical, they are not patentably distinct from each other because '075 claims a method of improving the tissue quality of an animal, including ruminant animals, using mixed tocotrienols. See claims 1, 10, and 13.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Lanari, M. C., et al., *Effect of Dietary tocopherols and tocotrienols on the antioxidant status and lipid stability of chicken*, MEAT SCIENCE, vol. 68, pages 155-162 (2004).

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- Kang, Kyung R, et al., *Tocopherols, retinol and carotenes in chicken egg and tissues as influenced by dietary palm oil*, JOURNAL OF FOOD SCIENCE, vol. 63, no. 4, pages 592-596 (1998).
- U.S. Patent Nos. 6,610,867; 6,740,508; and 5,821,264.

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Response to Arguments

Applicants' arguments filed on 6 August 2010 have been fully considered but they are not persuasive.

Applicants argue that Eenennaam does not teach the different concentrations of tocotrienols that would be present when the transgenic plants are converted to a feed, nor does the reference teach the use of such compounds, i.e., mixed tocotrienols in a feed. See remarks, page 5.

As explained in the substantive rejection, examiner respectfully submits that Eenennaam teaches the production of transgenic plants which in turn may be processed to produce a feed, meal protein, or oil preparation designated for ruminant animals (see, e.g., col. 6, lines 48-6 and col. 34, line 30). Applicants have neither acknowledged nor addressed this teaching of Eenennaam.

With respect to mixed tocotrienols, as also explained in the substantive rejection, the reference teaches that one or more products of the tocopherol biosynthesis pathway, including any one or more of tocotrienols, alpha-tocotrienols, gamma-tocotrienols, delta-tocotrienols, and beta-tocotrienols are increased throughout an organism such as a plant, preferably in a seed (see col. 22, lines 52-56). This means

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that one, two, three, or all four tocotrienols of the tocopherol biosynthesis pathway are increased in the seed of the disclosed plants. This meets the definition of “mixed tocotrienols” cited in the instant specification. An example of a cereal grain plant which has been genetically modified in such a way is corn (see col. 13, lines 29-56; col. 22, lines 52-56, col. 38, line 60-col. 39, line 6; examples 1, 3, 4; and claims 17, 19, 28, 31, and 21), also being claimed instantly. Again, applicants have neither acknowledged nor rebutted this teaching of Eenennam.

Regarding specific concentrations of tocotrienols, the Ulrich reference was cited as evidence for tocotrienol levels in corn grain.

Applicants argue that the tocotrienol concentration ranges disclosed by Ulrich relate to an oil, not a feed. See remarks, page 5.

Examiner respectfully submits that the instant application does not provide a special definition of a “feed” which precludes seed derived oils, which are edible by animals. Additionally, Ulrich explicitly teaches an embodiment wherein the extracted corn oil is added to a food product (see p. [0015] and p. [0027]).

Applicants argue that instant claim 1 recites a method of feeding a diet comprising at least 150 ppm mixed tocotrienols and that the instant application states that an animal “diet” comprises a formula providing all nutrients required by the animal species. Thus, applicants argue, the oil taught by Ulrich is not a “diet” as recited in the instant claims. See remarks, page 5.

Examiner respectfully disagrees that the instant application discloses an animal diet comprises a formula providing all nutrients required by the animal species. This

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interpretation of the specification is broader than what is disclosed. This interpretation is recited specifically for the pigs that were used in examples 1 and 2. The instant specification does not provide a broad disclosure requiring that a diet comprise all nutrients required by the animal species.

The only portion providing some guidance as to what is included in a "diet" seems to be [0018] of the pre-grant publication. In this paragraph, the only requirement of a "diet" is that it contain about 50 to 500 ppm mixed tocotrienols. Optional ingredients include alpha-lipoic acid (LA), N-acetylcysteine (NAC) and/or other antioxidants. However, p. [0018] does not include a general teaching of "all nutrients required by the animal species".

Even if, *arguendo*, a "diet" were defined in the specification as "all nutrients required by the animal species", this amorphous and broad definition constitutes potentially millions of combinations of various ingredients that may be fed to an animal. As such, examiner respectfully submits that the specification does not preclude oilseed based oils from what may constitute a "diet". To the contrary, based on the requirements of p. [0018], an oil meets the requirements of a "diet" so long as it contains 50 to 500 ppm mixed tocotrienols. As explained in the substantive rejection, Ulrich shows that yellow corn oil contains 231 ppm of alpha-tocotrienol, 23 ppm of beta-tocotrienol, 1463 ppm of gamma-tocotrienol, and 63 ppm of delta-tocotrienol (see Table 3). Thus, the alpha, beta, and delta-tocotrienol of Ulrich meets the definition of "mixed tocotrienol" of the instant application, and the disclosed concentrations of these tocotrienols are within the range recited in instant claims 1 and 20. The claims do not

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specify which tocotrienols are required and the specification only requires that at least three (i.e., any three) of the four tocotrienols must be present; as such, a mixture of alpha, beta, and delta tocotrienol meets the requirements of the claims.

Applicants argue that based on how ppm is calculated, Ulrich's disclosure of an oil having 50-330 ppm for alpha tocopherol provides no commentary on the final concentration of the tocotrienol that would be present in a "diet". Thus, applicants argue, Ulrich provides no comment on the level of mixed tocotrienols in the feed of an animal diet. See remarks, page 6.

Examiner respectfully submits that the levels of tocotrienol disclosed by Ulrich from extractions of whole corn grain was provided in the rejection as evidence that the levels of tocotrienols in the corn produced in the Eenennaam reference which may be used as animal feed, would contain the levels of tocotrienols being claimed instantly. In other words, the 231 ppm of alpha-tocotrienol, 23 ppm of beta-tocotrienol, and 63 ppm of delta-tocotrienol extracted by Ulrich in yellow corn oil from whole corn grain is evidence that these levels of tocotrienols would be found in the whole corn grain produced by Eenennam, since there is nothing in the Eenennaam reference to suggest that fractions of the corn grain (as opposed to the whole corn grain) are being used to make the feed taught by Eenennaam.

Applicants argue that Ulrich teaches that there are not a finite number of identifiable and predictable animal feeds, but rather, that the desired end product nutrition requires addition of supplemental elements. See remarks, page 6.

Examiner respectfully submits that the combination of references applied in the rejection read on instant claims 1 and 20 as currently constructed. The claims (and the specification) provide no requirement of what constitutes a “diet” or “feed” other than the recited levels of “mixed tocotrienols”. The recited levels of "mixed tocotrienols" are taught by the combination of Eenennaam and Ulrich, as explained in the substantive rejection.

Applicants argue that Boronat groups all isoprenoids together as tocols or vitamin E and does not teach differences between these antioxidants. See remarks, page 7.

Examiner respectfully submits that the teachings of Boronat apply to the instant claims as they are currently constructed. Boronat teaches that tocotrienols (independent of tocopherols) are well known antioxidants and play an important role in protecting cells from free radical damage and prevention of many diseases and in anti-aging (see p. [0005]). Given the fact that “oxidative stability” is disclosed as a factor in the consideration of tissue quality in the instant specification (see p. [0020]), examiner respectfully submits that Boronat's teaching of tocotrienols as well known antioxidants would suggest to a person of ordinary skill in the art that administration of tocotrienols would result in improved tissue quality and oxidative stability.

Applicants argue that Examples 2 and 3 of the instant application suggest unexpected and superior properties. See remarks, page 8.

At the outset, it is noted that examiner could not find the specific ingredients contained in the control diet in Examples 2 and 3 disclosed in the instant specification.

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As such, it is not possible to determine if the results obtained in with the group given the MT supplement were really unexpected and superior.

Additionally, examiner could not find a list of all the ingredients added to the composition comprising the MT supplement. As such, it is not possible to determine if the results obtained were as a result of the MT supplement or some other undisclosed ingredient in the feed.

Applicants argue that the obviousness-type double patenting rejection over Application No. 11/153,463 should be withdrawn because the '463 application recites a method of improving the tissue quality of an animal comprising feeding the animal a diet comprising oleic acid and selected tocots. See remarks, pages 9 and 10.

As for the oleic acid, examiner respectfully submits that the instant claims use the open transition phrase "comprising", which does not preclude the use of oleic acid.

As for "selected tocots", as applicants indicate in the remarks, the '463 application defines "selected tocots" as, *inter alia*, one or more of the tocotrienols (see p. [0009]). The phrase "one or more" includes three (i.e., three out of the four tocotrienols – the definition given in the instant specification); as such, examiner respectfully submits that the provisional obviousness-type double patenting rejection is properly maintained.

Applicants argue that the obviousness-type double patenting rejection over Application No. 11/520,075 should be withdrawn because the '075 application recites a method of improving the tissue quality of an animal comprising feeding the animal a diet comprising oleic acid, tocots, and a non-tocol anti-oxidant. See remarks, pages 10-11.

As for the oleic acid and a non-tocol anti-oxidant, examiner respectfully submits that the instant claims use the open transition phrase "comprising", which does not preclude the use of oleic acid or a non-tocol anti-oxidant.

As for "tocols", the '075 application defines "tocols" as, *inter alia*, a mixture of two or more of the four known tocotrienols (see p. [0016]). The phrase "two or more" includes three (i.e., three out of the four tocotrienols – the definition given in the instant specification); as such, examiner respectfully submits that the provisional obviousness-type double patenting rejection is properly maintained.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615